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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,016	03/16/2005	Kazuhiro Matsumoto	2114-0113PUS1	9503

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EXAMINER

HOFFMAN, SUSAN COE

ART UNIT	PAPER NUMBER
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1655

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/14/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/521,016

Applicant(s)

MATSUMOTO ET AL.

Examiner

Susan Coe Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The response filed December 29, 2006, has been received. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 8-17 are pending.
3. In the reply filed on June 15, 2006 Applicant's election with traverse of Toki-shakuyaku-san with traverse.
4. Claims 8-17 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 103

5. Claims 8, 10, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,318,798 in view of JP 61033122 A and JP 11060504 for the reasons set forth in the previous Office action. English translations of JP '122 and JP '504 are provided.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that Tables 1-2 show that Examples 1 and 4 have unexpectedly superior properties in comparison with Comparative Examples 1-1, 1-2, 1-3, 4-1 and 4-4. Example 4 and its comparative examples deal with non-elected species Daio-kanzo-to. Examples for this non-elected species are not considered evidence of patentability of the elected species of Toki-shakuyaku-san because the ingredients in the two compositions are different. Example 1 and its comparative examples are related to the elected species of Toki-shakuyaku-san. Example 1 does show unexpectedly superior results in comparison with the comparative examples. However, these unexpected results are not considered to render the claims patentable because the claims are not commensurate in scope with the composition shown

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in Example 1. As discussed in MPEP 716.02(d), any showing of unexpected results must be commensurate in scope with the claims or provide evidence to support that the entirety of the claimed range is supported by the unexpected results. Example 1 has very specific ingredient amounts that are not required by the claims. Furthermore, broad claim 1 does not require silicic anhydride which is also an ingredient in Example 1 that appears to contribute to the superior characteristics of this composition. Thus, broad claim 1 is not considered allowable based on the showing on unexpected results for the composition of Example 1. *However, a claim with the same limitations set forth in Example 1 would be considered allowable.*

Applicant also argues that the claimed invention is patentable over the prior art because the references as combined do not specifically provide motivation to combine the claimed ingredients together. Applicant specifically argues that JP '122 does not teach combining cellulose glycolate with Kampo medicines. However, JP '122 does show that it was known in the art to use cellulose glycolate to improve the dissolution properties of crude herbal drugs such as ginseng (see translation). Based on this knowledge that was available, an artisan of ordinary skill would reasonably expect that cellulose glycolate could be used to improve the dissolution of the crude drugs taught in US '798. This reasonable expectation of success would provide motivation to modify the drugs in US '798 to include cellulose glycolate.

Applicant also argues that no evidence has been presented to show that the amount of each ingredient is a known result effective parameter that would be obvious to optimize. However, the art itself teaches the amount of the ingredients can be varied (see claims of US '798 and paragraph [16] of the translation of JP '504). "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

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ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, since the art teaches that the amount of the ingredients can be varied, the art acknowledges that ingredient amount is a result effective parameter that can be optimized. An artisan of ordinary skill would be motivated to modify the ingredient amount in order to be achieve the results set forth by the combination of the references. Therefore, the claims are still considered properly rejected for the reasons of record.

6. Claims 9, 11, 13, 14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,318,798 in view of JP 61033122 A and JP 11060504 as applied to claims 8, 10, 12, and 15 above, and further in view of JP 56152416 A for the reasons set forth in the previous Office action. The English language translation of JP '416 is provided.

Applicant argues this rejection in combination with the rejection based on US '798, JP '122 and JP '504. The response to these arguments is as above.

7. No claims are allowed. However, allowable subject matter is indicated in paragraph 5.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

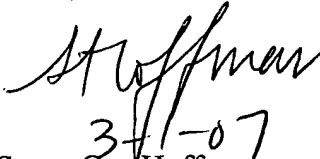
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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


34-07
Susan Coe Hoffman
Primary Examiner
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